## UNITED STATES PATENT AND TRADEMARK OFFICE



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WASHINGTON, D.C. 2023 I
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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,452,808

Stephen Venetianer, Esquire SmithKline Beecham Corporation 709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,452,808, which claims the human drug product REQUIP® (ropinirole), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within <u>one month</u> of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 21, 1998 (63 Fed. Reg. 70411). Under 35 U.S.C. § 156(c):

Period of Extension = 
$$\frac{1}{2}$$
 (Testing Phase) + Approval Phase  
=  $\frac{1}{2}(2,729 - 0) + 627$   
= 1,992 days (5.5 years)

Since the regulatory review period began on July 14, 1988, after the patent issue date (June 5, 1984), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation because the regulatory review period for the product began after the date of enactment of 35 U.S.C. § 156 (September 24, 1984). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,452,808

Granted: June 5, 1984

Original Expiration Date<sup>1</sup>: December 7, 2002

<sup>&</sup>lt;sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Applicant:

Gregory Gallagher, Jr.

Owner of Record:

SmithKline Beecham Corporation

Title:

4-Aminoalkyl-2(3H)-Indolones

Classification:

424/274

Product Trade Name:

REQUIP® (ropinirole)

Term Extended:

Five years

**Expiration Date:** 

December 7, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail:

Commissioner for Patents

By FAX:

(703) 872-9411

Box Patent Ext.

Attn: Office of Patent Legal Administration

Washington, D.C. 20231

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

· cc:

David T. Read

Acting Director Health Assessment Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7

Rockville, MD 20852

RE: REQUIP (ropinirole) FDA Docket No.: 98E-0478